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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,194	12/06/2001	Kevin P. Baker	GNE.2830P1C6	3544

30313 7590 03/22/2004

KNOBBE, MARTENS, OLSON & BEAR, LLP
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IRVINE, CA 92614

EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,194	BAKER ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/30/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendment canceling claims 1-27 and adding new claims 28-33, filed on 06 December 2001 is acknowledged.

Thus claims 28-33 are pending and under consideration.

2. ***Priority:***

2a. Based on the information given by Applicants and an inspection of the patent applications, the Examiner has concluded that the subject matter defined in this application is supported by the disclosure in application serial no. 09/946,374 filed on 04 September 2001, because, EXAMPLE 150 (Assay #110), which provides a specific and substantial asserted utility or a well established utility for the claimed antibodies, is disclosed on page 512 of Application no. 09/946,374. However, none of the other prior applications disclose this assay. Accordingly, the subject matter defined in claims 27-33, is afforded an effective filing date of 04 September 2001, which is the filing date of the U.S application No. 09/946,374.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to 09/04/01, which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 09/04/01.

Claim rejections-35 USC § 112, second paragraph:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3a. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "specifically" recited in instant claim 33 is a relative term which renders the claims indefinite. The term "specifically" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. §102(b):

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5a. Claims 28-33 are rejected under U.S.C. § 102 (a) as being anticipated by Baker et al (WO200012708; published 09 March 2000).

Baker et al disclose an isolated polypeptide that shares 100% homology to the polypeptide of SEQ ID NO:116 of the instant application. (See attached copies of the comparison of SEQ ID NO:116 of the instant invention and the sequence of the reference (SEQUENCE COMPARISON 'A'). Baker et al also disclose an antibody that binds to said polypeptide, (page 104-105). Baker et al disclose an antibody fragment, a

monoclonal antibody and a humanized antibody, that bind to a polypeptide that shares 100% identity to the polypeptide of SEQ ID NO:116, (pages 366-369).

Instant claims 28-33 are drawn to an antibody (monoclonal, fragment, humanized or labeled) that binds to the polypeptide of SEQ ID NO:116. Therefore, the Baker et al reference meets all the limitations recited in claims 28-33, because the antibody disclosed in this reference would be expected to bind completely to the polypeptide of SEQ ID NO:116 of the instant application. Therefore, the Baker et al reference anticipates the instant claims 28-33 in the absence of any evidence to the contrary.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Claim Rejections - 35 U.S.C. §102(a):

A person shall be entitled to a patent unless –

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6a. Claims 28-33 are rejected under U.S.C. § 102 (a) as being anticipated by Yang et al (WO200151638; published 19 July 2001).

Yang et al disclose an isolated polypeptide that shares 100% homology to the polypeptide of SEQ ID NO:116 of the instant application. (See attached copies of the comparison of SEQ ID NO:116 of the instant invention and the sequence of the reference (SEQUENCE COMPARISON 'B'). Yang et al also disclose an antibody that binds to said polypeptide, (page 32). Yang et al disclose an antibody fragment, a monoclonal antibody and a humanized antibody, that bind to a polypeptide that shares 100% identity to the polypeptide of SEQ ID NO:116 (pages 61-62).

Instant claims 28-33 are drawn to an antibody (monoclonal, fragment, humanized or labeled) that binds to the polypeptide of SEQ ID NO:116. Therefore, the Yang et al reference meets all the limitations recited in claims 28-33, because the antibody disclosed in this reference would be expected to bind completely to the polypeptide of SEQ ID NO:116 of the instant application. Therefore, the Yang et al reference anticipates the instant claims 28-33 in the absence of any evidence to the contrary.

Conclusion:

7. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
18 March 2004

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

ALIGNMENTS

Sequence Comparison "A"

RESULT 1
AAY99372
ID AAY99372 standard; Protein; 331 AA.
XX
AC AAY99372;
XX
DT 08-AUG-2000 (first entry)
XX
DE Human PRO1430 (UNQ736) amino acid sequence SEQ ID NO:116.
XX
KW Human; PRO polypeptide; membrane bound protein; receptor; diagnosis;
KW transmembrane; secretion; immunoadhesion; pharmaceutical; screening.
XX
OS Homo sapiens.
XX
PN WO200012708-A2.
XX
PD 09-MAR-2000.
XX
PF 01-SEP-1999; 99WO-US20111.
XX
PR 01-SEP-1998; 98US-0098716.
PR 01-SEP-1998; 98US-0098749.
PR 01-SEP-1998; 98US-0098750.
PR 02-SEP-1998; 98US-0098803.
PR 02-SEP-1998; 98US-0098821.
PR 02-SEP-1998; 98US-0098843.
PR 09-SEP-1998; 98US-0099536.
PR 09-SEP-1998; 98US-0099596.
PR 09-SEP-1998; 98US-0099598.
PR 09-SEP-1998; 98US-0099602.
PR 09-SEP-1998; 98US-0099642.

XX
PA (GETH) GENENTECH INC.
XX
PI Baker K, Goddard A, Gurney AL, Smith V, Watanabe CK, Wood WI;
XX
DR WPI; 2000-237871/20.
DR N-PSDB; AAA37054.
XX
PT New mammalian DNA sequences encoding transmembrane, receptor or
PT secreted PRO polypeptides, useful for screening of potential peptide or
PT small molecule inhibitors of the relevant receptor/ligand interactions
XX
PS Claim 12; Fig 66; 773pp; English.
XX
CC AAA37022 to AAA37144 encode the new isolated human transmembrane,
CC receptor or secreted PRO polypeptides given in AAY99340 to AAY99462. The
CC transmembrane and receptor PRO proteins can be used for screening of
CC potential peptide or small molecule inhibitors of the relevant
CC receptor/ligand interactions. The polypeptides and nucleotide sequences
CC encoding then have various industrial applications, including uses as
CC pharmaceutical and diagnostic agents. AAA37145 to AAA37330 represent
CC PCR primers and hybridisation probes used in the isolation of the PRO
CC polypeptides from the present invention.
XX
SQ Sequence 331 AA;

Query Match 100.0%; Score 1695; DB 21; Length 331;
Best Local Similarity 100.0%; Pred. No. 4.5e-166;
Matches 331; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

```
Qy          1 MSRYLLPLSALGTVAGAAVLLKDYVTGGACPSKATIPGKTVIVTGANTGIGKQTALELAR 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MSRYLLPLSALGTVAGAAVLLKDYVTGGACPSKATIPGKTVIVTGANTGIGKQTALELAR 60

Qy         61 RGGNIILACRDMEKCEAAAKDIRGETLNHHVNARHLDLASLKSIREFAAKIIEEEERVDI 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 RGGNIILACRDMEKCEAAAKDIRGETLNHHVNARHLDLASLKSIREFAAKIIEEEERVDI 120

Qy        121 LINNAGVMRCPHWTTEDGFEMQFGVNHLGHFLLTNLLLDKLKASAPSRIINLSSLAHVAG 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 LINNAGVMRCPHWTTEDGFEMQFGVNHLGHFLLTNLLLDKLKASAPSRIINLSSLAHVAG 180

Qy        181 HIDFDDLNWQTRKYNTKAAYCQSKLAIVLFTKELSRRLQGSGVTVNALHPGVARTELGRH 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 HIDFDDLNWQTRKYNTKAAYCQSKLAIVLFTKELSRRLQGSGVTVNALHPGVARTELGRH 240

Qy        241 TGIHGSTFSSTTLGPIFWLLVKSPELAAQPSTYLAVAEELADVSGKYFDGLKQKAPAPEA 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 TGIHGSTFSSTTLGPIFWLLVKSPELAAQPSTYLAVAEELADVSGKYFDGLKQKAPAPEA 300

Qy        301 EDEEVARRLWAESARLVGLEAPSVREQPLPR 331
              ||||||||||||||||||||||||||||||
Db        301 EDEEVARRLWAESARLVGLEAPSVREQPLPR 331
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Sequence Comparison "B"

RESULT 2
AAE05174
ID AAE05174 standard; Protein; 331 AA.
XX
AC AAE05174;
XX
DT 12-SEP-2001 (first entry)
XX
DE Human drug metabolising enzyme (DME-5) protein.
XX
KW Human; drug metabolising enzyme; DME-5; immunosuppressive; gene therapy;
KW cytostatic; autoimmune disorder; inflammatory disorder; atherosclerosis;
KW osteoporosis; eye disorder; hepatic tumour; Addison's disease; cretinism;
KW rheumatoid arthritis; acquired immune deficiency syndrome; AIDS; anaemia;
KW developmental disorder; endocrine disorder; iritis; acromegaly; epilepsy;
KW thyrotoxicosis; pancreatic disorder; diabetes mellitus; obesity; adenoma;
KW gastrointestinal disorder; nodular hyperplasia; conjunctivitis; glaucoma;
KW actinic keratosis; metabolic disorder; dysphagia; anorexia; carcinoma;
KW cell proliferative disorder.
XX
OS Homo sapiens.
XX
FH Key   Location/Qualifiers
FT Peptide   1..17
FT   /label= Signal_peptide
FT Protein   18..331
FT   /note= "Mature drug metabolising enzyme (DME-5) protein"
XX
PN WO200151638-A2.
XX
PD 19-JUL-2001.
XX
PF 12-JAN-2001; 2001WO-US01174.
XX
PR 14-JAN-2000; 2000US-0176139.
PR 21-JAN-2000; 2000US-0177443.
PR 28-JAN-2000; 2000US-0178574.
XX
PA (INCY-) INCYTE GENOMICS INC.
XX
PI Yang J, Baughn MR, Burford N, Au-Young J, Lu DAM, Reddy R;
PI Ring HZ, Hillman JL, Yue H, Azimzai Y, Yao MG, Gandhi AR;
PI Nguyen DB, Tang YT, Lal P, Bandman O;
XX
DR WPI; 2001-425874/45.
DR N-PSDB; AAD09940.
XX
PT Drug metabolizing enzymes and encoding polynucleotides, useful for
PT diagnosing, treating and/or preventing autoimmune, inflammatory, cell
PT proliferative, developmental, endocrine, eye, metabolic, and
1   PT gastrointestinal disorders -
XX
PS Claim 1; Page 139-140; 133pp; English.

XX
CC The present sequence is human drug metabolising enzyme (DME-5) protein.
CC Human DME and its nucleic acid molecule are useful for the diagnosis,
CC treatment and prevention of disorders associated with increased or
CC decreased expression of DME. Examples of such disorders include,
CC autoimmune/inflammatory disorder such as acquired immune deficiency
CC syndrome (AIDS), rheumatoid arthritis, osteoporosis; cell proliferative
CC disorder such as actinic keratosis, atherosclerosis; developmental
CC disorder such as epilepsy, anaemia; endocrine disorder such as
CC acromegaly, cretinism, thyrotoxicosis; pancreatic disorder such as
CC diabetes mellitus; eye disorder such as conjunctivitis, glaucoma, iritis;
CC metabolic disorder such as Addison's disease, obesity; gastrointestinal
CC disorder such as anorexia, dysphagia and hepatic tumours including
CC nodular hyperplasia, adenomas and carcinomas. DME DNA is useful for
CC creating 'knockin' humanised animals (pigs) or transgenic animals (mice
CC or rats) to model human disease. DME DNA is also in useful is gene
CC therapy. DME and its immunogenic fragments are useful for screening
CC libraries of compounds in several drug screening assays.
XX
SQ Sequence 331 AA;

Query Match 100.0%; Score 1695; DB 22; Length 331;
Best Local Similarity 100.0%; Pred. No. 4.5e-166;
Matches 331; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy          1 MSRYLLPLSALGTVAGAAVLLKDYVTGGACPSKATIPGKTVIVTGANTGIGKQTALELAR 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MSRYLLPLSALGTVAGAAVLLKDYVTGGACPSKATIPGKTVIVTGANTGIGKQTALELAR 60

Qy         61 RGGNIILACRDMEKCEAAAKDIRGETLNHHVNARHLDLASLKSIREFAAKIIEEEERVDI 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 RGGNIILACRDMEKCEAAAKDIRGETLNHHVNARHLDLASLKSIREFAAKIIEEEERVDI 120

Qy        121 LINNAGVMRCPHWTTEDGFEMQFGVNHLGHFLLTNLLLDKLKASAPSRIINLSSLAHVAG 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 LINNAGVMRCPHWTTEDGFEMQFGVNHLGHFLLTNLLLDKLKASAPSRIINLSSLAHVAG 180

Qy        181 HIDFDDLNWQTRKYNTKAAYCQSKLAIVLFTKELSRRLQGSGVTVNALHPGVARTELGRH 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 HIDFDDLNWQTRKYNTKAAYCQSKLAIVLFTKELSRRLQGSGVTVNALHPGVARTELGRH 240

Qy        241 TGIHGSTFSSTTLGPIFWLLVKSPELAAQPSTYLAVAEELADVSGKYFDGLKQKAPAPEA 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 TGIHGSTFSSTTLGPIFWLLVKSPELAAQPSTYLAVAEELADVSGKYFDGLKQKAPAPEA 300

Qy        301 EDEEVARRLWAESARLVGLEAPSVREQPLPR 331
              ||||||||||||||||||||||||||||||
Db        301 EDEEVARRLWAESARLVGLEAPSVREQPLPR 331
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